

JAN 18 2005

510(k) Summary

Tyco Healthcare/Kendall *DOVER*[®] Silver Temperature Sensing Foley Catheter

In accordance with section 513(l) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Tyco Healthcare/Kendall
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: September 28, 2004

1. Contact Person

Wei Zhao
Senior Specialist, Regulatory Affairs
Tyco Healthcare/Kendall
Telephone: (508) 261-8404
Fax: (508) 261-8461

2. Name of Medical Device

Classification Name:	Catheter, Retention Type, Balloon
Common or Usual Name:	Urinary Drainage Silicone Foley Catheter with Temperature Sensor
Trade Name:	Tyco Healthcare/Kendall <i>DOVER</i> [®] Silver Temperature Sensing Foley Catheter

3. Identification of Legally Marketed Device

The proposed *DOVER*[®] Silver Temperature Sensing Foley Catheter is identical in intended uses, function and mode of operation to the currently marketed *DOVER*[®] 100% Silicone Foley Catheter with Temperature sensor and *DOVER*[®] Silver Hydrogel Coated Silicone Foley Catheter. *DOVER*[®] 100% Silicone Foley Catheter with Temperature sensor was cleared for marketing under 510(k) K933400. *DOVER*[®] Silver Hydrogel Coated Silicone Foley Catheter was cleared for marketing under 510(k) K024010.

4. Device Description

The Tyco Healthcare/Kendall *DOVER*[®] Silver Temperature Sensing Foley Catheter is a sterile, single use, indwelling urinary drainage catheter extruded from 100% vulcanized silicone material. The catheter is coated with a lubricious hydrophilic topcoat containing an inorganic silver releasing polymer.

4. Device Intended Use

The proposed device is intended for use in the drainage/collection of urine from the urinary bladder and simultaneous monitoring of the body core temperature during surgical or post-surgical intervals. General drainage is accomplished by inserting the catheter through the urethra and into the bladder. The catheter is retained in the bladder by inflation of balloon. Efficacy of the *DOVER*[®] Silver Temperature Sensing Foley Catheter in preventing urinary tract infection during the catheterization has not been established. This device is not intended to be used as a treatment for active urinary tract infection.

5. Product Comparison

The proposed *DOVER*[®] Silver Temperature Sensing Foley Catheter is substantially equivalent to the Tyco healthcare/Kendall *DOVER*[®] 100% Silicone Foley Catheter with Temperature sensor as each product is intended for use in the drainage/collection of urine from the urinary bladder and simultaneous monitoring of the body core temperature. Also the proposed device is substantially equivalent to the Tyco healthcare/Kendall *DOVER*[®] Silver Hydrogel Coated Silicone Foley Catheter as each product has a Foley catheter with same silver hydrogel coating and is intended for use in the drainage/collection of urine from the urinary bladder.

6. Nonclinical Testing

Biocompatibility testing has demonstrated that the proposed device meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.

End of Document



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 18 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Wei Zhao
Senior Regulatory Specialist
Tyco Healthcare/Kendall
15 Hampshire Street
MANSFIELD MA 02048

Re: K042709
Trade/Device Name: *DOVER® Silver Temperature Sensing Foley Catheter*
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 EZL
Dated: December 23, 2004
Received: December 27, 2004

Dear Ms. Zhao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement

510 (k) Number (if known): K042709

Device Name:

Tyco Healthcare/Kendall *DOVER*[®] Silver Temperature Sensing Foley Catheter

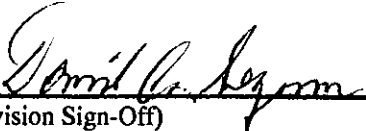
Indications for Use:

The proposed catheters are intended for use in the drainage/collection of urine from the urinary bladder and simultaneous monitoring of the body core temperature during surgical or post-surgical intervals. General drainage is accomplished by inserting the catheter through the urethra and into the urine bladder. The catheter is retained in the bladder by inflation of balloon. Drainage is sometimes accomplished by suprapubic or other placement of the catheter.

Please DO NOT Write Below This Line – Continue On Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR OVER-The -Counter Use (Per 21 CFR 801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042709